UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,489	01/07/2005	Alan Breen	34655-703.831	6542

21971 7590 10/09/2007

WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
BOR, HELENE CATHERINE	
ART UNIT	**PAPER NUMBER**
3768	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,489	BREEN, ALAN	
	Examiner	Art Unit	
	Helene Bor	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner recognizes the applicant's amendments to claims 9, 15 and 24. Under examination are the original and amended claims 9-32.

Response to Arguments

1. Applicant's corrections, filed 06/12/2007, with respect to the oath/declaration are accepted. All objections to the drawings are withdrawn.

2. Applicant's corrections, filed 06/12/2007, with respect to the abstract are accepted. All objections to the drawings are withdrawn.

3. Applicant's corrections, filed 06/12/2007, with respect to the drawings are accepted. All objections to the drawings are withdrawn.

4. Applicant's corrections, filed 06/12/2007, with respect to the specification are accepted. All objections to the specification are withdrawn.

5. Applicant's amendments, filed 06/12/2007, with respect to the claims are accepted. The claim rejection under 35 U.S.C. § 112 is withdrawn.

6. Applicant's arguments filed 06/12/2007 have been fully considered but they are not persuasive. The applicant's argues nothing within Vortruba'859 would lead a person of ordinary skill in the art to an apparatus for the measurement of skeletal joint motion, which includes a means for real time digital sampling of the images of the moving joints. Examiner agrees that Vortruba'859 doesn't teach real-time digital sampling of the images of the moving joint. However, Bejjani'042 does teach means for real time digital sampling of the images of the moving joints (Col. 3, Line 2-8 & (Col. 5, Line 29-36). It would have been obvious to one of ordinary skill in the art to combine the teachings of

Vortruba'859 and Bejjani'042 in order to take advantage of a processing system that increases the amount of data derived from the recorded images (Col. 2, Line 15-17). It appears applicant currently claims "continuous" to overcome the prior art. In the application, however, the applicant on states, "Methods of the present invention...permit accurate measurement of the small ranges of segmental motion throughout the range of flexion/extension (Page 9, Lines 13-17). Please note that multiple segmental imaging be tantamount to continuous imaging.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 9 & 11-13 and rejected under 35 U.S.C. 103(a) as being unpatentable over Votruba'859 (US Patent No. 5,899,856) in view of Bejjani042 (US Patent No. 5,090,042).

Claim 9: Votruba'859 teaches a passive motion device (Figure 9) for continuously moving a joint (Col. 6, Line 24-32) which comprises a horizontal platform base (Figure 9, Element 29) and a horizontal passive motion platform (Figure 9, Element 6 & 25) composed of a horizontal static platform (Figure 9, Element 25) which is rigidly connected to the upper lateral surface of the platform base (Figure 9, Element 29) and a horizontal laterally movable platform (Figure 9, Element 6) which is flexibly connected to the static platform (Figure 9, Element 25), in which the static platform (Figure 9, Element 25) is adjacent to the laterally movable platform (Figure 9, Element 6) which together both form the passive motion platform (Figure 9, Element 6 & 25), in which the movement of the laterally movable platform (Figure 9, Element 6) continuously is driven during use by a motor (Figure 1, Element 9) attached to the platform base (Figure 9, Element 29) where movement of the laterally movable platform (Figure 9, Element 6) is achieved by means of a control arm (Figure 9, Element 19) that operably connects the laterally moveable platform (Figure 9, Element 6) to the motor (Figure 1, Element 9). Votruba'859 teaches an imaging device (Figure 16, Element 101).

Votruba'859 fails to teach in detail the processing system. However, Bejjani'042 teaches a processing system which comprises a computer incorporating a means for real time digital sampling of images of the continuously moving joints during a continuous movement of the joint (Col. 3, Line 36-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bejjani'042 and Votruba'859, in order to take advantage of a processing system that

increases the amount of data derived from the recorded images (Col. 2, Line 15-17). Bejjani'042 teaches the means for recording time code (Col. 5, Line 4-8) and data from the passive motion platform during the continuous movement of the passive motion platform (Col. 5, Line 27-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bejjani'042 and Votruba'859 in order to take advantage of the data being processed, manipulated and restored over time (Col. 5, Line 29-36). In addition, that such means allow for the automation of the process and eliminates the need for manually conversion and so saves time (Col. 5, Line 40-45). Bejjani'042 teaches means for storage of these images at high resolution (Col. 4, Line 42-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bejjani'042 and Votruba'859 for the benefit of the stored motion data later being retrieved from memory for viewing and analysis (Col. 6, Line 16-17). Bejjani'042 teaches means for recognising templates attributed to individual bones (Col. 4, Line 3-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bejjani'042 and Votruba'859 for the benefit of displaying in real-time motion, review or analysis (Col. 3, Line 3-8). Bejjani'042 teaches means for tracking these automatically using cross- correlation functions and means for geometric transformation of the positional data to graphically display their relative motion over time (Col. 6, Line 16-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bejjani'042 and Votruba'859 in order to take advantage of the greater level of information (Col. 6, Line 30-34).

Claim 11: Votruba'859 teaches the imaging device is a magnetic resonance scanner (Figure 16, Element 101).

Claim 12: Votruba'859 teaches in which the laterally movable platform (Figure 9, Element 6) is situated on a support which lies on the upper surface of the platform base (Figure 9, Element 29).

Claim 13: Votruba'859 fails to teach where the imaging device is an X-ray tube. However, Bell'859 teaches the use of and x-ray with an image intensifier and the dose control (Col. 6, Line 1-9) for the use of imaging in-vivo motion. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 in order to reveal more information (Col. 1, Line 30-36).

10. Claim 10 & 14 - 32 and rejected under 35 U.S.C. 103(a) as being unpatentable over Votruba'859 (US Patent No. 5,899,856) in view of Bejjani042 (US Patent No. 5,090,042) and further in view of Bell'859 (US Patent No. 5,099,859).

Claim 10: Votruba'859 fails to teach where the imaging device is an X-ray tube. However, Bell'859 teaches the use of and x-ray with an image intensifier and the dose control (Col. 6, Line 1-9) for the use of imaging in-vivo motion. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 in order to reveal more information (Col. 1, Line 30-36).

Claim 14: Votruba'859 teaches the imaging device is a magnetic resonance scanner (Figure Element 101).

Claim 15: Votruba'859 the automated measurement method of the relative motion of skeletal structures in vivo (Col. 2, Line 26-28). Votruba'859 teaches to position the subject on a passive motion device (Figure 16, Element 31). Votruba'859 teaches initiating the imaging procedure of the subject positioned on the passive motion device and collecting image data using an imaging device (Col. 6, Line 39-54). Votruba'859 teaches sampling the data collected by the imaging device into the processing system (Col. 6, Line 39-62)

Votruba'859 fails to teach the imaging processing aspect of the claimed invention. However, Bejjani'042 teaches superimposing time code on the images for the benefit of proper time registration and play-back (Col. 5, Line 4-8). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 in order to take advantage of record keeping and documentation as well as tracking patient exposure (Col. 7, Line 22-27 & Col. 7, Line 55-62). Bejjani'042 teaches tracking templates marked on individual bone segments at the start of the motion sequence (Col. 4, Line 3-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 for the benefit of motion analysis and defining points of interest (Col. 4, Line 20 – 45). Bell'859 teaches transforming the results of tracking to reflect the changing spatial relationship between image segments (Col. 4, Line 32-40 & Col. 11, Line 32-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 for the benefit of permitting the standardization of

interpretations of skeletal studies (Col. 4, Line 29-31). Bell'859 teaches presenting the output in graphical form (Col. 6, Line 1-21, Figure 5 & Figure 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 for the benefit of permitting the standardization of interpretations of skeletal studies (Col. 4, Line 29-31).

Claim 16: Votruba'859 fails to teach where the imaging device is an X-ray tube. However, Bell'859 teaches the use of and x-ray with an image intensifier and the dose control (Col. 6, Line 1-9) for the use of imaging in-vivo motion. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 Bell'859 in order to reveal more information (Col. 1, Line 30-36).

Claim 17: Votruba'859 teaches the imaging device is a magnetic resonance scanner (Figure Element 101).

Claim 18: Votruba'859 teaches in which the laterally movable platform (Figure 9, Element 6) is situated on a support which lies on the upper surface of the platform base (Figure 9, Element 29).

Claim 19: Votruba'859 fails to teach where the imaging device is an X-ray tube. However, Bell'859 teaches the use of and x-ray with an image intensifier and the dose control (Col. 6, Line 1-9) for the use of imaging in-vivo motion. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 in order to reveal more information (Col. 1, Line 30-36).

Claim 20: Votruba'859 teaches the imaging device is a magnetic resonance scanner (Figure Element 101).

Claim 22: Votruba'859 teaches the relative motion of lumbar vertebrae L3 to L3, L3 to L4 and L4 to L5 (Col. 8, Line 26-43). Votruba'859 fails to teach tracking the lumbar vertebrae simultaneously or separately. However, Bejjani'042 teaches tracking of the cervical vertebrae such as C4, C5, or C6 either simultaneously or separately as determined by the operators (Col. 4, Line 23-27 & Figure 1, Element P1, P2, P3). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 for the benefit of standardizing of interpretations of skeletal studies (Col. 4, Line 29-31).

Claim 24: Votruba'859 fails to teach the diagnosis of a pseudoarthrosis in a subject. However, Bejjani'042 teaches the diagnosis of many internal conditions of the spine, which would include pseudoarthrosis, through the analysis of the relative motion of skeletal structures (Col. 6, Line 39-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 for the benefit of an accurate evaluation (Col. 6, Line 39-51).

Claim 25: Votruba'859 fails to teach where the imaging device is an X-ray tube. However, Bell'859 teaches the use of and x-ray with an image intensifier and the dose control (Col. 6, Line 1-9) for the use of imaging in-vivo motion. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the

teachings of Bell'859, Bejjani'042 and Votruba'859 in order to reveal more information (Col. 1, Line 30-36).

Claim 26: Votruba'859 teaches the imaging device is a magnetic resonance scanner (Figure Element 101).

Claim 27: Votruba'859 teaches in which the laterally movable platform (Figure 9, Element 6) is situated on a support which lies on the upper surface of the platform base (Figure 9, Element 29).

Claim 28: Votruba'859 fails to teach where the imaging device is an X-ray tube. However, Bell'859 teaches the use of and x-ray with an image intensifier and the dose control (Col. 6, Line 1-9) for the use of imaging in-vivo motion. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042 and Votruba'859 in order to reveal more information (Col. 1, Line 30-36).

Claim 29: Votruba'859 teaches the imaging device is a magnetic resonance scanner (Figure Element 101).

Claim 31: Votruba'859 teaches the relative motion of lumbar vertebrae L3 to L3, L3 to L4 and L4 to L5 (Col. 8, Line 26-43). Votruba'859 fails to teach tracking the lumbar vertebrae simultaneously or separately. However, Bejjani'042 teaches tracking of the cervical vertebrae such as C4, C5, or C6 either simultaneously or separately as determined by the operators (Col. 4, Line 23-27 & Figure 1, Element P1, P2, P3). It would have been obvious to one of ordinary skill in the art at the time of the invention to

combine the teachings of Bell'859, Bejjani'042 and Votruba'859 for benefit of standardizing of interpretations of skeletal studies (Col. 4, Line 29-31).

11. Claim 21, 23, 30 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Votruba'859 (US Patent No. 5,899,856) in view of Bejjani042 (US Patent No. 5,090,042), in view of Bell'859 (US Patent No. 5,099,859) and further in view of McGregor'060 (US Patent No. 5,891,060).

Claim 21: Votruba'859 fails to teach a calibration step is carried out prior to the method of claim 15. However, McGregor'060 teaches the calibration step is carried out prior to the start of the procedure (Col. 16, Line 53 – Col. 17, Line 32). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042, McGregor'060 and Votruba'859 in order to provide verification (Col. 16, Line 53 – Col. 17, Line 32).

Claim 23: Votruba'859 teaches the relative motion of lumbar vertebrae L3 to L3, L3 to L4 and L4 to L5 (Col. 8, Line 26-43). Votruba'859 fails to teach tracking the lumbar vertebrae simultaneously or separately. However, Bejjani'042 teaches tracking of the cervical vertebrae such as C4, C5, or C6 either simultaneously or separately as determined by the operators (Col. 4, Line 23-27 & Figure 1, Element P1, P2, P3). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042, McGregor'060 and Votruba'859 for the benefit of standardizing of interpretations of skeletal studies (Col. 4, Line 29-31).

Claim 30: Votruba'859 fails to teach a calibration step is carried out prior to the method of claim 15. However, McGregor'060 teaches the calibration step is carried out

prior to the start of the procedure (Col. 16, Line 53 – Col. 17, Line 32). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042, McGregor'060 and Votruba'859 in order to provide verification (Col. 16, Line 53 – Col. 17, Line 32).

Claim 32: Votruba'859 teaches the relative motion of lumbar vertebrae L3 to L3, L3 to L4 and L4 to L5 (Col. 8, Line 26-43). Votruba'859 fails to teach tracking the lumbar vertebrae simultaneously or separately. However, Bejjani'042 teaches tracking of the cervical vertebrae such as C4, C5, or C6 either simultaneously or separately as determined by the operators (Col. 4, Line 23-27 & Figure 1, Element P1, P2, P3). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Bell'859, Bejjani'042, McGregor'060 and Votruba'859 for the benefit of standardizing of interpretations of skeletal studies (Col. 4, Line 29-31).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER